



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

January 7, 2005

**FILE COPY**

Mr. Monte R. Browder  
IVAX Pharmaceuticals, Inc.  
4400 Biscayne Boulevard  
Miami, Florida 33137

Dear Mr. Browder:

Your petition requesting the Food and Drug Administration to not approve ANDAs for simvastatin tablets, 5mg, 10mg, 20mg and 40 mg until IPI's 180-day exclusivity under ANDA No. 76-052 has expired, was received by this office on 01/06/2005. It was assigned docket 2005P-0008/CP 1 and it was filed on 01/07/2005. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe  
Division of Dockets Management  
Office of Management Programs  
Office of Management

2005P-0008

ACK1